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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,643	08/21/2003	Adrian Liem	4-32682A	8789

1095 7590 04/21/2005

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,643	LIEM ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JFL

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 22-21 filed on January 12, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-20 and 23-35 have been cancelled.

Specification

2. The use of the trademarks have been noted in this application. See for example, page 10. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. The specification should be reviewed for these types of informalities and correction is required.

3. The specification is objected to because page 6 of the specification fails to disclose the ATCC number of the biological deposit. Correction is required.

It should be noted that Morck et al., *(U.S. Patent 6,241, 992 B1 published June 5, 2001 (filed September 1998))* teach that footrot is also known as interdigital phlegmon, interdigital necrobacillosis, foot abscess, foul-in-the-foot or superfoul (column 5).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 21-22 are rejected under 35 U.S.C. 102(a) as anticipated by Liem et al *(32nd Annual Convention Proceedings, American Association of Bovine Practitioners September 23-26, 1999, Nashville, TN).*

Claims 21-22 are drawn to a method of preventing footrot and liver abscesses in bovines caused by infection with *Fusobacterium necrophorum* bacteria, wherein said method is comprised of:

(a) growing an isolate of *Fusobacterium necrophorum* bacteria, taken from a bovine species, for successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture having a bacterial count population equal to at least 1×10^5 CFU/ml,

(b) forming a vaccine by combining said bacteria culture with an amount of diluent, and

(c) administering at least one dosage of said vaccine subcutaneously to a bovine subject, with said dosage of about 1 ml to about 2 ml.

Liem et al teach a method of preventing footrot and liver abscesses in bovines by subcutaneously administering to bovine a FUSOGARD™ vaccine comprising *Fusobacterium necrophorum* bacterin (page 262). Liem et al teach that 2 ml of the vaccine was administered initially and again after 60 days (pages 263-264). The claim limitation "growing an isolate of *Fusobacterium necrophorum* bacteria, taken from a bovine species, for successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture having a bacterial count population equal to at least 1 x 10^5 CFU/ml" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 21-22 are rejected under 35 U.S.C. 102(b)as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berg (*EP 0406480 B1, published January 24, 1996).*

Claims 21-22 are drawn to a method of preventing footrot and liver abscesses in bovines caused by infection with *Fusobacterium necrophorum* bacteria, wherein said method is comprised of:

(a) growing an isolate of *Fusobacterium necrophorum* bacteria, taken from a bovine species, for successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium*

necrophorum bacteria whole cell culture, with said bacteria culture having a bacterial count population equal to at least 1 x 10^5 CFU/ml,

(b) forming a vaccine by combining said bacteria culture with an amount of diluent, and

(c) administering at least one dosage of said vaccine subcutaneously to a bovine subject, with said dosage of about 1 ml to about 2 ml.

Berg teaches a method of preventing footrot and liver abscesses in bovine by vaccinating bovine with a vaccine composition comprising *Fusobacterium necrophorum* (page 4). Berg teaches that the isolates used in the vaccine composition were cultured between 10 and 24 hours (page 3). Berg et al teach that cattle (bovine) may be administered the vaccine compositions by subcutaneous injection (page 3). Berg teaches that a dose of a bout 1 ml to about 6 ml is suitable for vaccinating cattle or sheep (page 3). Berg teaches that multiple injections of the vaccine composition may be administered to animals (a series of at least 2 injections)(page 3). The claim limitation "said bacteria culture having a bacterial count population equal to at least 1 x 10^5 CFU/ml" would be inherent in the teachings of the prior art.

Berg do not specifically disclose a isolates taken from a bovine. Berg teaches that the isolates were isolated from sheep however, the invention is not limited to bacterins derived from a specific isolate ; because these isolates exhibit characteristics which are typical of all biovar (biotype A of *F. necrophorum* (page 3). It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add

isolates taken from bovine to the vaccine composition used in the claimed method because Berg teaches that isolates of the invention exhibit characteristics which are typical of all biovar (biotype A of *F. necrophorum* (page 3).

Pertinent Prior Art

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Berg *(U.S. Patent No. 6132, 709 published October 17, 2000).*

Status of Claims

7. No claims allowed.

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
April 12, 2005

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